

EXHIBIT 4



April 16, 2015

By First Class and Electronic Mail

Matthew P. Moriarty
Tucker Ellis
950 Main Avenue, Suite 1100
Cleveland, OH 44113
matthew.moriarty@tuckerellis.com

Norton Rose Fulbright US LLP
98 San Jacinto Boulevard, Suite 1100
Austin, Texas 78701-4255
United States

Adam T. Schramek
Partner
Direct line +1 512 536 5232
adam.schramek@nortonrosefulbright.com

Tel +1 512 474 5201
Fax +1 512 536 4598
nortonrosefulbright.com

**Re: New England Compounding Pharmacy, Inc. Products Liability Litigation
Saint Thomas Entities' Comparative Fault Discovery to Ameridose**

Dear Mr. Moriarty:

I write on behalf of Saint Thomas Health, Saint Thomas Network and Saint Thomas West Hospital f/k/a St. Thomas Hospital ("Saint Thomas Entities") in response to the discovery responses you served on behalf of Ameridose, LLC ("Ameridose") on April 8, 2015, and the accompanying letter.

Your discovery responses provide little more than stock objections based on a misunderstanding of the scope of the limited, narrow stay on discovery your client obtained in exchange for agreeing to pay millions of dollars to settle its potential liability for the contaminated steroids at issue in this MDL. The Saint Thomas Entities are permitted to seek the full scope and breadth of discovery under the federal rules of civil procedure with respect to any remaining claim or defense in the cases pending against them.

As you know from the status conferences you have attended, the Saint Thomas Entities have asserted as an affirmative defense the comparative fault of several parties and non-parties. As further reflected by their master answer (Docket #1464), they assert that the following persons or entities caused or contributed to cause the injuries about which Plaintiffs complain, and accordingly should be apportioned their percentage of fault at trial under applicable Tennessee law:

1. NECC (pp. 56 to 61);
2. Ameridose (pp. 61 to 66);
3. Alaunus (pp. 66 to 69);
4. Barry Cadden (pp. 69 to 74);
5. Lisa Conigliaro Cadden (pp. 74 to 78);
6. Douglas Conigliaro (pp. 78 to 82);

April 16, 2015
Page 2

^NORTON ROSE FULBRIGHT

7. Gregory Conigliaro (pp. 82 to 85);
8. Carla Conigliaro (pp. 85 to 89);
9. Glenn Chin (pp. 89 to 93);
10. GDC Properties Management, LLC (pp. 93 to 94);
11. Medical Sales Management, Inc. and Medical Sales Management SW, Inc. (pp. 94 to 99);
12. John Notarianni and Mario Giamei (pp. 99 to 101);
13. the Food and Drug Administration ("FDA") (pp. 101 to 108);
14. the Massachusetts Board of Registration in Pharmacy ("MBP") (pp. 108 to 114);
15. the Tennessee Board of Pharmacy (pp. 114 to 115);
16. the Tennessee Department of Health (pp. 115 to 117);
17. Liberty Industries, Inc. (p. 117);
18. UniFirst Corporation (pp. 117-118);
19. ARL BioPharma, Inc. (pp. 118-120);

The discovery requests served on Ameridose are aimed not only at discovering evidence of Ameridose's fault for the injuries at issue, but for discovering evidence of the fault of the numerous other parties and non-parties listed above.

With respect to Ameridose's own fault, its discovery responses are at best evasive, and at worst misleading. Take, for example, document request number twenty-four. The Saint Thomas Entities asked for all documents referring or relating to the pass thru "box" depicted in the documents Bates labeled 003489-003491, which were attached. Ameridose first objects that the request exceeds the scope of discovery (i.e., the limited stay), and then claims the request is irrelevant because Ameridose did not compound the MPA "at or from any Ameridose facility."

The attached documents reflect a pass thru box that was manufactured and installed by Liberty Industries (one of the parties to which the Saint Thomas Entities have alleged comparative fault) in the large, main cleanroom being used by NECC in 2012 to compound the MPA at issue in this litigation. However, this cleanroom was constructed **at the direction and under the supervision of Ameridose**. See Deposition of J. Erickson at 133:2 to 134:17; 183:1 to 183:12. The drawings for the pass thru box likewise confirm that the pass thru at issue was the **"Ameridose pass thru."** In the letter, Liberty suggests that the "concept works" (i.e., a pass thru hooked up to a conveyor belt) but that the decision "as to how and when to proceed belongs to the customer" (i.e., Ameridose). *Id.* at 196:11 to 196:13. The pass-thru was ultimately installed **without the automatic sliding door**. When Liberty was questioned as to why the sliding door was not installed, its head engineer testified that the customer (i.e.,

April 16, 2015
Page 3

^NORTON ROSE FULBRIGHT

Ameridose) never ordered it. *Id.* at 197:19 to 198:12. This Ameridose cleanroom, designed and apparently approved by Ameridose with an open pass-thru and conveyor belt, was ultimately used to compound the tainted steroids. The Saint Thomas Entities are clearly entitled to discovery from Ameridose regarding these circumstances, including discovery of additional documents relating to the design, construction and approval of the NECC cleanrooms. The discovery relates not only to Ameridose's own fault, but that of Liberty (which installed the pass-thru without the required sliding door) and NECC (which failed to correct Liberty's and Ameridose's "open" conveyor belt design despite warnings of contamination). Ameridose's objections to the contrary are groundless.

Importantly, none of these facts would have ever been discovered if Ameridose's approach to discovery had been taken by Liberty. It is only because Liberty realized such objections would be groundless that a small crack was made in the stockpile of relevant documents Ameridose is apparently sitting on but refuses to review or produce.

Similarly, the discovery relating to commingling of funds and management is not intended to pierce the corporate veil or prove agency or alter ego, as your letter suggests. The Saint Thomas Entities have not pled, and do not seek, to disregard the separate structure of Ameridose or attempt to hold it responsible for someone else's actions. To the contrary, they intend to list Ameridose as a separate line on the jury charge next to NECC. The discovery regarding commingling of funds, sharing of business and the like is relevant to determining the extent to which Ameridose and its owners improperly profited from NECC, having set it up with a conveyor belt to maximize production but no door to shut out contaminants. The "significance of what the person was attempting to accomplish" is one factor a jury considers in determining comparative fault. See T.P.I. 3.52. And importantly, this is merely the discovery phase; actual admissibility will be determined much later. Right now, we only have to establish that materials requested are likely to lead to the discovery of admissible evidence.

The discovery requests regarding Ameridose's history with the FDA and MBP are aimed at discovering documents relating to the comparative fault claims asserted in the Saint Thomas Entities' answer against those regulatory bodies. See FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities, Staff Report, Committee on Energy and Commerce, April 16, 2013, available at <http://docs.house.gov/meetings/IF/IF02/20130416/100668/HHRG-113-IF02-20130416-SD101.pdf>. It is not the Saint Thomas Entities, but members of the United States House of Representatives, who have concluded that the regulatory history of Ameridose is relevant to the actions the regulators should have taken against NECC. See, e.g., *id.* at p. 21 ("Like NECC, its sister company, Ameridose, had a significant history with FDA. FDA was well aware of the **firms' shared ownership and management**. On several occasions, **this factored into FDA's decision-making** about whether and when to take certain actions related to one of the companies."). These are the same type of arguments the Saint Thomas Entities will make at trial, not in an attempt to pierce the corporate veil, but in an attempt to establish that the FDA and MBP should be allocated fault for failing to take actions that would have prevented the contamination of the steroids at issue.

In addition, discovery regarding Ameridose's compounding practices are relevant to the fault of NECC and the individuals working at NECC and/or Ameridose, particularly in light of the FDA's conclusion regarding the importance of the shared ownership and management of these sister companies. For example, the Saint Thomas Entities are entitled at the discovery phase to

April 16, 2015
Page 4

^NORTON ROSE FULBRIGHT

inquire into whether Ameridose had different policies and procedures in place at NECC, which unlike Ameridose was not an FDA-registered manufacturer, and if so, why. Ultimately, there are a number of possible arguments the Saint Thomas Entities and their trial attorneys may make to a jury regarding these facts and circumstances, but piercing the corporate veil is not one of them (for the reasons you, and we previously, cited).

With respect to whom Ameridose should identify as its corporate representative, we believe the facts currently known point to Mr. Cadden as an appropriate person. Plus, Mr. Cadden's deposition has already been noticed. Accordingly, formally designating him as Ameridose's corporate representative on the deposition topics requested will be the least burdensome on the company.

With respect to your concern that you do not have anyone to verify Ameridose's interrogatory responses, we believe Mr. Cadden's designation prior to his deposition as Ameridose's corporate representative will resolve that issue too. I note that in similar circumstances, courts have permitted the deposition of the attorney drafting the interrogatory responses. *Compare Ameridose's Response to Interrogatory #1 with Tailored Lighting, Inc. v. Osram Sylvania Prods.*, 255 F.R.D. 340, 345 (W.D.N.Y. 2009) (compelling the deposition of a party's attorney to identify (1) the information relied upon in answering the interrogatories; (2) the particular source (person or record) of that information; and (3) non-privileged communications between [the attorney] and his human sources about that information that occurred in the course of investigating and answering the interrogatories). I am confident that, working together, we can avoid that result.

While there are many more examples of Ameridose's improper discovery responses (such as the claim that it cannot answer whether it "shared a booth" with NECC because it does not understand what that means), I will not belabor those points here. Instead, I will simply ask you to withdraw your objections and 1) produce all non-privileged documents responsive to our document requests that are located pursuant to the search process required by the ESI Protocol, and 2) present a corporate representative (or designate Mr. Cadden) for deposition on such documents and the topics listed in my prior letter. If you will agree to do this, we will withdraw our requests for admission and interrogatories. Please let me know no later than **Wednesday, April 22nd**, if you will agree to proceed as suggested.

I turn next to the requirements of the ESI Protocol previously entered by the Court [Docket #1087], which was carefully tailored to make sure all responsive documents are located and produced at the least expense possible. With respect to the financial burden you claim Ameridose would suffer if it had to process all of the hard drives that exist, we certainly understand such concern and treat your letter as refusing to search any hard drives per Section III of the ESI Protocol and instead proposing to limit searches to the e-mail server previously imaged. You did not propose any limitations on custodians.

Please treat this letter as being in furtherance of our mutual obligation to meet and confer with you pursuant to the ESI Order in an attempt to reach agreement on search terms, data sources and exclusion criteria. While we cannot agree at this time to limit search terms to the e-mail server, we are open to the discussion. In particular, please provide us with an index or listing of the hard drives you possess along with any information you have on the source, custodian and content of each drive so that we can determine which of the hard drives the Saint Thomas Entities will agree to exclude from the search terms we hopefully can agree upon.

April 16, 2015
Page 5

^NORTON ROSE FULBRIGHT

With respect to the search terms to be applied to the data sources ultimately agreed upon or ordered by the Court, attached to this letter are the terms we propose running on the e-mail server and hard drives. Pursuant to Section III, I am hopeful we can reach agreement on terms and data sources by May 9, 2015, the 30th day after you served your discovery responses.

If you would like to continue this discussion by phone, please send me some proposed times.

Very truly yours,



Adam T. Schramek

Ameridose Search Terms (4/16/15)

FDA	pass-thru or "pass thru"
"good manufacturing practices"	victory
MBOP or MBP or "Board of Pharmacy"	pressure
USP	"inches of water" or "in of water"
ISO	HVAC
certif*	ARL or "Analytical Research Laboratories"
NECC	"not sterile"
conference or convention	alaunus
booth	policies or procedures
MPA	recycling or mattress or foam
Methylprednisolone	unlicensed or "not licensed"
autoclave	
contamin*	
test*	
fungal or fungus	
mold	
expired	
unifirst	
uniclean	
"cleaning crew" or "cleaning people"	
"cleaning solutions"	
liberty	
conveyor	